

DOCKETS MANAGEMENT BRANCH (HFA-305)
FOOD AND DRUG ADMINISTRATION
5630 FISHERS LANE ROOM 1061
ROCKVILLE, MD 20857-0003

7 8 4 5 '99 JUL 26 AIO :20

24497

RE: DOCKET NO. 98N-1265

To the FDA:

I send this letter as a consumer of health care services to register my concern and disapproval of the Memorandum of Understanding as published by the FDA on January 21, 1999.

In its present form, the MOU, as well as the Compounding Section 503A of the Modernization² Act, severely restricts the rights of the physicians and patients to obtain healthcare products from the provider of their choice. It also infringes on the rights of compounding pharmacists to serve the public's medical needs. As a healthcare consumer there should be no restrictions to the delivery of compounded medication prescribed for me, regardless of where I live or travel. The MOU must be amended!!!

The FDA is an agency of the U.S. Government that purports to be the "watchdog" for consumer safety. THIS IS NOT A SAFETY ISSUE!! As a governmental agency, the FDA also has a responsibility to be accountable to the people. Once again, the MOU must be amended!!

Comments:

On 2 occasions in the past 20 years I had to give up taking hormone therapy because it made me seriously ill. A compounded^{medication} prescribed for me by my doctor has improved my overall health over the past 4 years. I beg you not to take that health benefit away from me.

Signed: Cherie Halbardier

State of Residence: New York

98N-1265

H

Claire Halbardier
750 Columbus Ave Apt 7A
New York, NY 10025-6478



ockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane Room 1061
Rockville MD 20857-0003

20857/0003

